

OCT 27 2005

510(K) SUMMARY

K052895

fourSight ViewTool image viewer

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. Submitted By:

Siemens Medical Solutions USA, Inc., Ultrasound Division
1230 Shorebird Way
Mountain View, CA 94043

Contact Person:

Patrick J Lynch
Regulatory Affairs

Phone: (425) 557-1825
FAX: (425) 391-9198

Date Prepared:

September 21, 2005

2. Proprietary Name:

fourSight ViewTool

Common/ Usual Name:

System, Image Processing, Radiological

Classification Name:

21 CFR 892.2050

Picture Archiving and Communications System FR # 892.2050 Product Code 90-LLZ

3. Predicate Device:

- K050034, 01/13/2005, ACUSON Antares ultrasound systems
- K022896, 10/02/2002, CSV12 Viewer Software

4. Device Description:

The ViewTool is used to view volumes and images, to store and print images, and to make measurements on images using a personal computer. The software is user-installable. The images are acquired by ultrasound systems using standardized formatting and are transferred from the ultrasound system to the PC hosting the ViewTool software by CD-ROM.

5. Intended Uses:

Acceptance, transfer, display, storage, and digital processing of diagnostic ultrasound images. Image manipulation and quantification.

6. Technological Comparison to Predicate Device:

The FourSight ViewTool is substantially equivalent to the ACUSON Antares, cleared via K050034, the CSV12 Software Viewer, cleared via K022896. The ViewTool is used to view volumes and images, to store and print images, and to make measurements on images using a personal computer. The software is user-installable. The images are acquired by ultrasound systems using standardized formatting and are transferred from the ultrasound system to the PC hosting the ViewTool software by CD-ROM.

End of 510(k) Summary



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2005

Siemens Medical Solutions, USA
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K052895
Trade/Device Name: *fourSight™* ViewTool
image viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 11, 2005
Received: October 14, 2005

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052895

Device Name: fourSight™ ViewTool image viewer

Indications for Use:

The intended use of the *fourSight* ViewTool is for the acceptance, transfer, display, storage, and digital processing of ultrasound images, including image manipulation and quantification.

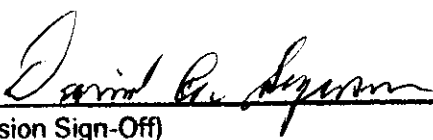
Prescription Use X
(Part 21 CFR 801 Subpart D)

~~AND/OR~~

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052895

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(Posted November 13, 2003)